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| | APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------|------------------------------------|---------------------------|----------------------|---------------------------------|------------------|
| | 08/765,244 | 10/30/1997 | PETER SEIBEL | 8484-018-999 | 5827 |
| | 23713 7: | 590 07/30/2003 | | | |
| | | E WINNER AND SULLIVAN P C | | EXAMINER | |
| | 5370 MANHATTAN CIRCLE SUITE 201 | | | LACOURCIERE, KAREN A | |
| BOULDER, CO 80303 | | O 80303 | | ART UNIT | PAPER NUMBER |
| | | | | 1635 DATE MAILED: 07/30/2003 | 28 |
| | | | | | - 0 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|
| | 08/765,244 | SEIBEL ET AL. | | | | |
| Office Action Summary | Examin r | Art Unit | | | | |
| | Karen A. Lacourciere | 1635 | | | | |
| The MAILING DATE of this c mmunication appears n the cover sheet with the c rrespondence address P riod for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
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| _ | is action is non-final. | | | | | |
| , | | osecution as to the merits is | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| 4) Claim(s) 84-130 is/are pending in the applicat | ion. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 84-130 are subject to restriction and/o | or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | e drawing(s) be held in abeyance. Se | ee 37 CFR 1.85(a). | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign | 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents | 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachm nt(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) ratent Application (PTO-152) | | | | |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03-14-2003 has been entered.

Specification

The substitute specification filed March 14, 2003 is acceptable and has been entered and is sufficient to overcome the objections to the specification set forth in the prior Office actions because it adds sequence identifiers, an abstract and a priority statement.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on March 14, 2003 has been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

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Election/Restrictions

In the submission filed March 14, 2003, Applicant's amendments cancel all pending claims and submit all new claims which are drawn to multiple inventions. As a result of these new claims, a restriction requirement is set forth herein.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 84-104, drawn to a chimeric peptide nucleic acid construct,
 wherein the nucleic acid is linear, classified in class 536, subclass 24.5.
- II. Claims 105-128 and 131-134, drawn to a chimeric peptide nucleic acid construct wherein the construct comprises a cyclic nucleic acid molecule, classified in class 536, subclass 23.1.
- III. Claims 129 and 130, drawn to a method of making a chimeric peptide nucleic acid construct, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different modes of operation. Inventions I and II are materially different compositions, with different structures, for example, the nucleic acid portion of the constructs of Group I are linear, whereas the nucleic acid portion of the compositions of Group II are cyclic. Due to these structural differences, the constructs operate through different mechanisms and provide different effects.

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Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making can be used to produce a materially different product, for example, it can be used to make a cyclic nucleic acid construct or a construct with additional nucleic acid components, providing a product which is materially different by structure. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of making can be used to produce a materially different product, for example, it can be used to make a linear nucleic acid construct or a construct with additional nucleic acid components, providing a product which is materially different by structure.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Restriction to one sequence further required for Group I

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Applicant should elect Group I, a further restriction is imposed to elect one single sequence, either SEQ ID NO:1 or 22. Each of these sequences is directed to a distinct invention in that each has a unique and distinct amino acid sequence. Further, a search for more than one of these sequences would put an undue search burden on the office and, therefore, an election of one single sequence is required.

Because these inventions are distinct for the reasons given above and the search required for SEQ ID NO:1 is not required for SEQ ID NO:22, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by

a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Karen A. Lacourciere whose telephone number is (703)

308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone

numbers for the organization where this application or proceeding is assigned are (703)

308-4242 for regular communications and (703) 305-1935 for After Final

communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703) 308-

0196.

Karen A. Lacourciere

July 28, 2003

AREN LACOURCIERE

PATENT EXAMINER